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510(k) Summary

JUN 29 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street, Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 03/16/2010

2.0 Device information

Device name: KD-5965 series Fully Automatic Electronic Blood Pressure Monitor
Model No: KD-5965XY(X =A~Z, Y= blank or A~Z)

The model in KD-5965 series are the modification to KD-5965, and the modification will rise no new 510(k) according to FDA's guidance document < Deciding When to Submit a 510(k) for a Change to an Existing Device>.

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predict device information

1	Manufacturer:	Andon Health Co., Ltd.
	Device:	KD-5905 Fully Automatic Electronic Blood Pressure Monitor
	510(k) number:	K090770
2	Manufacturer:	Andon Health Co., Ltd.
	Device:	KD-5963 Fully Automatic Electronic Blood Pressure Monitor

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	510(k) number: K093528

5.0 Device description

KD-5965 series Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

It is designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

For KD-5965, the operational principle is based on oscillometric and silicon integrate pressure sensor technology, the result will be shown on a LCD with an electronic interface module, the result can also be classified and displayed by the function of blood pressure classification indicator, the memory capability is 60 times. If any irregular heartbeat is detected, it can be shown on the LCD. The LCD backlight, the touch key button and the voice function make it more convenient to use. The RCC (radio controlled clock) function can automatically receive the radio clock signal to adjust the clock accurately.

6.0 Intended use

KD-5965 series Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of KD-5965 series, as described in its labeling are the same as the predict device KD-5905 or KD-5963.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical

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Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

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8.0 Performance summary

KD-5965 series Fully Automatic Electronic Blood Pressure Monitor will conform to the following standards before marketing:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 --, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 --, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

9.0 Comparison to the predict device and the conclusion

Our device KD-5965 Fully Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-5905 whose 510(k) number is K090770 and the Fully Automatic Electronic Blood Pressure Monitor KD-5963 with the 510(k) number of K093528.

The KD-5965 is very similar with the predicted devices in the intended use, the design principle, the material, the energy source and the applicable standards. Only their appearance is different, moreover, the KD-5965 uses different MCU from the two predicted devices.

However, appropriate test will be conducted and specified acceptance criteria will be met before KD-5965 is marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2010

Andon Health Co., Ltd.
c/o Ms. Liu Yi
President
No. 3 JinPing Street, Ya An Road, NanKai District
Tianjin 300190
CHINA

Re: K100940
Trade/Device Name: KD-5965 Series Fully Automatic Electronic Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: May 27, 2010
Received: June 1, 2010

Dear Ms. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

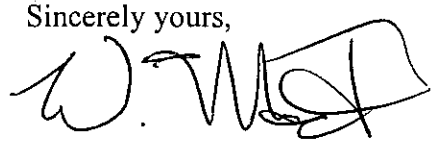
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : _____

Device name: KD-5965 series Fully Automatic Electronic Blood Pressure Monitor

Indications for use:

KD-5965 series Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES
Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100940